

REMARKS

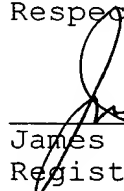
Entry of the amendments to the specification, claims and abstract before examination of the application is respectfully requested. These claims patentably define over the art of record.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #1850/49685).

Respectfully submitted,

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Marked-Up of Specification  
PCT/EP99/06019  
Attorney Docket No. 1850/49685

# SYSTEM FOR THE CARE OF CONTACT LENSES

## BACKGROUND OF THE INVENTION

[0001] This application claims the priority of PCT International No. PCT/EP99/06019 filed August 17, 1999 and German Patent Document No. 198 43 140.6, filed September 21, 1998, the disclosures of which are expressly incorporated by reference herein.

[0002] The invention relates to a system for the maintenance and care of contact lenses [according to the preamble of Claim 1] having a receptacle, a hydrous H<sub>2</sub> O<sub>2</sub> -solution and a catalyst with a platinum film.

[0003] In the case of such a system known from [German Patent Document] DE 196 24 095 C1, a receptacle is provided in which, for the maintenance and care of contact lenses, a 3% H<sub>2</sub>O<sub>2</sub>-solution is provided for disinfecting contact lenses. The contact lens is immersed in this solution for treatment and storage. For the neutralization of the hydrous hydrogen peroxide solution, a platinum [layer] film is situated on a molded body made of glass, which platinum [layer] film may also be provided as an internal coating of the receptacle

consisting of glass.

[0004] For the maintenance and care of contact lenses, in addition to the disinfecting effect, the antimicrobial and antiviral effectiveness and a sufficient preservation are, however, also important, particularly when the contact lens is stored in the care solution for some time, which occurs, for example, in the case of adaptation or soft [(or soft?-translator)] contact lenses (DE 196 01 568 A1).

[0005] The oligodynamic effect, that is, the growth-inhibiting or killing effect of heavy metals, particularly of silver, on microorganisms is known. It was found, however, that, when using silver (silvering) of the initially mentioned care system in the conventional manner, the durability of the platinum catalyst was impaired and the platinum [layer] film catalysts had to be replaced after a short time.

#### SUMMARY OF THE INVENTION

[0006] It is therefore an object of the invention to provide a system [of the initially mentioned type] which, in addition to the [oligodynamics] oligodynamic effectiveness of the maintenance and care system, ensures a long durability of the platinum [layer] film catalyst.

[0007] According to the invention, this object is achieved by [the characterizing features of Claim 1] applying a silver layer applied to a carrier, the silver layer being in a direct contact with the hydrous H<sub>2</sub>O<sub>2</sub>-solution filled in the container by way of a surface which is less than about 30 mm<sup>2</sup>/ml.

[0008] The invention is based on the recognition that the durability of the platinum [layer] film catalyst is not negatively impaired if the entire silver surface, which is effective in the hydrogen peroxide solution, does not exceed an upper limit. This upper limit is in the order of up to 25 mm<sup>2</sup>/ml of the H<sub>2</sub>O<sub>2</sub> solution charged into the receptacle. The hydrous H<sub>2</sub>O<sub>2</sub>-solution is preferably a physiological solution with a physiological pH-value (approximately 6 to 8). Also in this solution, the desired antimicrobial long-term effectiveness is achieved by [means of] the silver metal layer which preferably is uniform and exists on a carrier. Within the disinfection phase (2 to 6 hours), after an inoculation with 10<sup>5</sup> to 10<sup>6</sup> KBE/ml of the test germs provided in the International Standard Draft ISO/CD 14729 (pseudomonas aeruginosa, staphylococcus aureus, serratia marcescens, candida albicans and fusarium solani) and, in addition,

aspergillus niger at the end of the disinfection phase, no growth was found, or a germ reduction by at least 5 powers of ten (5 log) was determined. After an inoculation with the poliovirus, a reduction to under the detection limit was obtained within 60 minutes. After the inoculation with the adenovirus a > 3 log reduction was obtained within 120 minutes; after 240 minutes, a >4.5 log reduction (virus below the detection limit) was obtained. After an inoculation with the HSV 1-virus, a > 3 log reduction (virus below detection limit) occurred within 30 minutes.

[0009] As a result, a single-stage system is created for the disinfection and preservation of contact lenses which is very effective during the disinfection and, during the storage of contact lenses, ensures [prevents? translator] that their microbic contamination is prevented without the use of preservatives.

[0010] In a preferred manner, a silver surface is used of approximately 0.2 to 0.6, particularly 0.3 mm<sup>2</sup>/ml, of the hydrous H<sub>2</sub>O<sub>2</sub> solution (3%) charged into the receptacle.

[0011] The silver layer with the indicated surface can be provided on a contact lens hold-down device by [means of] way

of which the contact lens is immersed in the solution. This hold-down device can in a known manner be provided on the underside of a closing cover by which the receptacle is covered. By [means] way of the hold-down device, it is prevented that, as a result of the gases forming during the contact lens care and the neutralization of the care solution, the contact lens to be treated is driven to the surface of the care solution, but remains constantly immersed in the care solution.

[0012] The system for the care of contact lenses can be constructed as described in [German Patent Document] DE 197 57 356.8 A1. In this case, the receptacle, which receives the hydrous  $H_2O_2$ -solution and the contact lens, can consist of glass and be coated on its interior side with a platinum layer catalyst. The platinum layer can be applied by sputtering. However, it is also possible to provide a molded body made of glass, which is provided with a platinum layer, in the receptacle [German Patent Document] (DE 196 24 095 C1). The silver layer will then preferably be situated on the contact lens hold-down device, which is provided with bores so that the care solution will be present also over the hold-down surface which is immersed in the solution.

[0013] In another embodiment, the contact lens hold-down device can consist of glass whereby, on one side of the hold-down device, particularly the underside, the platinum layer is arranged which is preferably applied by sputtering, and on the other side, particularly the top side of the hold-down device, the silver layer [being] is arranged which can also be applied by sputtering. The receptacle can then also consist of plastic.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0014] [The invention will be explained by embodiment by means of the drawings.]

[0015] Figure 1 is a schematic view of a first embodiment of the present invention; and

[0016] Figure 2 is a schematic view of a second embodiment of the present invention.

#### DETAILED DESCRIPTION OF THE DRAWINGS

[0017] In the embodiments of Figures 1 and 2, two cup-shaped receptacles 1, which are liquid-tight, are arranged in [a case 4 in] two receiving compartments 5 of [the] a case 4. Each receptacle 1 is used for receiving and for the care of a

contact lens. On the exterior side of each receiving compartment 5, a thread is provided at the upper edge of the case 4, onto which thread a cover 3 can be screwed. However, it is also possible to provide a different holding device for the cover on the case, such as a clip-on device, holding clamps, or the like. As a result, a liquid-tight connection is established between the cover and the case. Inside the receiving compartments 5, the respective receptacles 1 are held at a distance from the cover underside and from the interior side of the respective receiving compartment 5. As a result, a space or spaces is/are created between the respective upper edge 6 of the receptacle and between the respective exterior side of the receptacle and the interior side of the respective receiving compartment 5 [, which] .  
The space or spaces form(s) a passage for gases which are formed in the respective receptacles during the contact lens care. At the respective case 4, a bottom is provided on the underside. The case preferably consists of plastic. The bottom may also consist of plastic, particularly of metallized plastic, or of metal. As described in [German Patent Document] DE 197 57 356.8, the bottom may be fastened to the case 4 in a removable manner, for example, by [means of] a snap-on connection. As a result, it is ensured that gas, which is formed during the care of the contact lenses and



during their storage in the receptacle, can escape through the created spaces.

[0018] In the illustrated embodiments, one hold-down device 6 respectively is provided. The hold-down device 6 has a hold-down surface which is immersed in the charged care solution. The care solution consists of a 3%  $H_2O_2$ -solution. As a result of the effect of this care solution, the immersed contact lenses are disinfected. In order to avoid hydrogen peroxide residue on the contact lenses after the care, as a result of the effect of a platinum layer 2, the hydrogen peroxide is decomposed into oxygen and hydrogen (neutralized).

[0019] In the embodiment of Figure 1, the platinum layer 2 is situated on the interior side of the receptacle 1 consisting of glass. On the hold-down device 6, a silver layer 7 is situated which, similar to the platinum layer 2, can be applied by sputtering to the top side of the hold-down device 6. The hold-down device 6 has bores, so that the care solution can penetrate through the hold-down surface and it is ensured that the contact lens immersed by the hold-down surface will be situated below the surface of the charged care solution. The applied silver layer 7 is also always situated within the filling volume of the charged care solution. As a

result, an oligodynamic effect of the solution is achieved during the disinfection phase, in which the hydrogen peroxide has an effect, as well as after the neutralization of the hydrogen peroxide solution.

[0020] In the embodiment of Figure 2, the platinum layer 2, which acts as a neutralization catalyst, is situated on the underside of the hold-down device 6. The silver layer 7 is situated on the top side of the hold-down device 6. In this embodiment of Figure 2, the hold-down device 6 is made of glass. The silver layer 7 is preferably produced by sputtering. The surface of the silver layer 7, which is in contact with the  $H_2O_2$ -solution, amounts to maximally 30 mm<sup>2</sup>/ml, relative to the filling volume of the  $H_2O_2$ -solution. In the embodiment of Figure 2, the receptacle 1 may consist of glass or of another material, such as plastic.

[0021] Instead of the hold-down device 6, small baskets can be used which are each provided on the underside of the cover 3 and carry the silver layer 7. The hold-down device and the small storage basket ensure that the contact lens is always immersed in the care solution. Gases forming during the neutralization and care steps cannot drive the lens to the surface of the care solution. As a result, a constant care of the immersed contact lens is achieved.

[0022] In the following Tables 1 and 2, the oligodynamic effect of different embodiments of the care system is illustrated in the case of various test organisms. In this case, neutralized hydrogen peroxide solutions (isotonic, pH 6.5, < 5 ppm residual content of hydrogen peroxide) are inoculated with approximately  $10^6$  microorganisms per ml of solution. Based on the tables, also in the case of relatively small silver layer surfaces (between 0.15 and 2.0 mm<sup>2</sup>/ml), the oligodynamic effect occurs which is achieved over a fairly long time period, which effect is important particularly for the care of adaptation [soft?] or soft contact lenses.

TABLE 1

| Test Organism                          | Ag Surface<br>[mm <sup>2</sup> /ml] | Initial Inoculum<br>[log (KBE/ml)] | Logarithmic reduction of test microorganisms<br>[log (KBE/Ausgangs-KBE)] |               |               |               |
|--|-------------------------------------|------------------------------------|--|---------------|---------------|---------------|
|  |                                     |                                    | 0 Hour   | 7 Hours       | 14 Days       | 28 Days       |
| Staphylococcus<br>aureus<br>ATCC 6538  | 0,62                                | 6,43                               | 0  | <-4,43 n.g.)  | <-4,43 (n.g.) | <-4,43 (n.g.) |
|  | 0,94                                | 6,43                               | 0  | <-4,43 (n.g.) | <-4,43 (n.g.) | <-4,43 (n.g.) |
|  | 1,88                                | 6,43                               | 0  | <-4,43 (n.g.) | <-4,43 (n.g.) | <-4,43 (n.g.) |
| Pseudomonas<br>aeruginosa<br>ATCC 9027 | 0,62                                | 6,54                               | 0  | -4,60         | -3,14         | <-4,54 (n.g.) |
|  | 0,94                                | 6,54                               | 0  | -5,08         | <-5,05        | <-5,54 (n.g.) |
|  | 1,88                                | 6,54                               | 0  | <-4,54 (n.g.) | <-4,54 (n.g.) | <-5,54 (n.g.) |
| Enterococcus<br>faecium<br>ATCC 6057   | 0,62                                | 6,20                               | 0  | -1,26         | -2,06         | <-4,20 (n.g.) |
|  | 0,94                                | 6,20                               | 0  | -1,20         | -2,63         | <-5,20 (n.g.) |
|  | 1,88                                | 6,20                               | 0  | -1,59         | <-4,20 (n.g.) | <-5,20 (n.g.) |

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|                  |      |      |   |               |               |               |
|------------------|------|------|---|---------------|---------------|---------------|
| Serratia         | 0,62 | 6,38 | 0 | <-4,38 (n.g.) | <-4,38 (n.g.) | <-5,38 (n.g.) |
| marcescens       | 0,94 | 6,38 | 0 | <-4,38 (n.g.) | <4,97         | <-4,89        |
| ATCC 13880       | 1,88 | 6,38 | 0 | <-4,38 (n.g.) | <-5,57        | <-5,38 (n.g.) |
| Candida albicans | 0,62 | 6,59 | 0 | -1,51         | <-4,59 (n.g.) | <-5,59        |
| ATCC 10231       | 0,94 | 6,59 | 0 | -2,53         | <-4,59 (n.g.) | <-5,59 (n.g.) |
|                  | 1,88 | 6,59 | 0 | <-4,59 (n.g.) | <-5,81        | <-5,59 (n.g.) |
| Aspergillus      | 0,62 | 6,65 | 0 | -1,55         | -1,96         | -2,14         |
| niger            | 0,94 | 6,65 | 0 | -1,53         | -1,75         | -1,92         |
| ATCC 16404       | 1,88 | 6,65 | 0 | -1,34         | -2,02         | -2,16         |
| Fusarium solani  | 0,62 | 6,40 | 0 | -2,74         | -3,49         | -4,40         |
|                  |      |      | 0 | -4,00         | <-4,40        | -5,10         |
|                  |      |      | 0 | <-4,40 (n.g.) | <-5,62        | <-5,40 (n.g.) |

\* Average value of a repeat determination

KBE: Number of the colony-forming unit

n.g.: no growth

Table 2

| Test Organism                       | Ag Surface<br>[mm <sup>2</sup> /ml] | Initial Inoculum<br>[log (KBE/ml)] | Logarithmic reduction of test microorganisms<br>[log (KBE/initial-KBE)] |                                 |   |   |
|-------------------------------------|-------------------------------------|------------------------------------|---|---------------------------------|---|---|
|                                     |                                     |                                    | 0 Hour  | 24 Hours                        | 7 Days  | 14 Days   |
| Staphylococcus aureus<br>ATCC 6538  | 0,15<br>0,30<br>0,60                | 5,95<br>5,95<br>5,95               | 0<br>0<br>0   | -1,00<br>-1,26<br>-0,50         | <-3,95 (n.g.)<br><-3,95 (n.g.)<br><-3,95 (n.g.) | <-3,95 (n.g.)<br><-3,95 (n.g.)<br><-3,95 (n.g.) |
| Pseudomonas aeruginosa<br>ATCC 9027 | 0,15<br>0,30<br>0,60                | 5,70<br>5,70<br>5,70               | 0<br>0<br>0   | -0,55<br>-1,51<br><-3,38        | -0,82<br><-2,74<br><-4,70 (n.g.)                | -1,25<br>-2,04<br><-4,70 (n.g.)                 |
| Escherichia coli<br>ATCC 8739       | 0,15<br>0,30<br>0,60                | 5,81<br>5,81<br>5,81               | 0<br>0<br>0   | -1,12<br>-1,83<br><-3,81 (n.g.) | <-4,40<br><-4,81 (n.g.)<br><-4,81 (n.g.)        | <-4,81 (n.g.)<br><-4,81 (n.g.)<br><-4,81 (n.g.) |

|                  |      |      |   |               |               |               |
|------------------|------|------|---|---------------|---------------|---------------|
| Serratia         | 0,15 | 5,78 | 0 | -3,12         | <-4,78 (n.g.) | <-4,78 (n.g.) |
| marcescens       | 0,30 | 5,78 | 0 | -0,85         | -2,23         | <-3,78 (n.g.) |
| ATCC 13880       | 0,60 | 5,78 | 0 | <-3,78 (n.g.) | <-4,78 (n.g.) | <-4,78 (n.g.) |
| Candida albicans | 0,15 | 6,00 | 0 | -0,91         | -2,82         | <-4,00 (n.g.) |
| ATCC 10231       | 0,30 | 6,00 | 0 | -0,57         | -1,02         | <-4,00 (n.g.) |
|                  | 0,60 | 6,00 | 0 | -0,95         | <-4,00 (n.g.) | <-4,00 (n.g.) |
| Aspergillus      | 0,15 | 6,70 | 0 | -2,40         | -2,43         | -2,18         |
| niger            | 0,30 | 6,70 | 0 | -2,30         | -2,25         | -2,20         |
| ATCC 16404       | 0,60 | 6,70 | 0 | -2,18         | -2,27         | -2,36         |

\* Average value of a repeat determination

KBE: Number of the colony-forming unit

n.g.: no growth

ABSTRACT:

A system for the care of contact lenses [,having] has a receptacle [1], a hydrous 3%  $\text{H}_2\text{O}_2$ -solution, which can be charged into the receptacle [1], and a catalyst consisting of a platinum layer [2] for the neutralization of the  $\text{H}_2\text{O}_2$ -solution [,in which]. The catalyst is in contact with its surface and the hydrous  $\text{H}_2\text{O}_2$ -solution, in which case, for improving the oligodynamic effect of the care solution, a silver layer [7] is in contact with the  $\text{H}_2\text{O}_2$ -solution, whose surface is maximally  $3.0 \text{ mm}^2/\text{ml}$ .

[Figure 1]